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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,647	10/28/1999	ROLAND SCHULE	SCH-1700	4945

23599 7590 03/08/2002

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/08/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding..

Office Action Summary

Application No.

09/428,647

Applicant(s)

SCHULE ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Formal matters

1. Claim 1 was amended, and new claims 13-15 were added, in Paper No. 9, 12/26/2001. Claims 10-12 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 1-9, 13-15 are under consideration.

Response to Amendment

2. The rejection of claims 1-9 under 35 USC § 102(e) has been withdrawn based on Applicant's amendment.

Specification

3. The incorporation of essential material in the specification by reference to a publication is improper, as set forth in Paper No. 8, 9/24/200. Applicant is required to amend the disclosure to include the material incorporated by reference. Applicant argues that the sequence of SLIM3 is available in the art. However, this document encompasses essential matter, and the sequence of the SLIM3 polypeptide is essential for the practice of a method which makes use of the SLIM3 polypeptide. Therefore, the above cited document encompasses essential subject matter, which cannot be incorporated by reference to publications (See MPEP 608.01(p)). Clearly, the amino acid sequence of the SLIM3 polypeptide is necessary to practice the claimed method.

Claim Rejections - 35 USC § 112 first paragraph

4. Claims 1-9, 13-15 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of identifying agents that regulate the transcriptional activating domain of human AR and human SLIM3, does not reasonably provide enablement for a method of identifying agents that regulate the transcriptional activating domain of human AR and biologically active fragments of human SLIM3, for reasons of record set forth in paper No. 8, 9/24/2001. Additionally, new claims 13-15 are rejected under 35 USC § 112 first paragraph as not reasonably providing enablement for a method of identifying agents that regulate the transcriptional activating domain of human AR and human SLIM3 or biologically active polypeptides having at least 90, 95 and 98% sequence identity thereto. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The basis of the rejection is that claims 1-9 and new claims 13-15 are overly broad in the recitation of "biologically active fragments" since insufficient guidance is provided as to which of the myriad of polypeptide species encompassed by the claim will retain the characteristics of SLIM3. The specification (page 11, line 29 to page 12 line 6) defines that SLIM3 derivatives are determined in that the function according to the examples of the SLIM3 that is described in the literature is compared to the modification. Applicants disclose that fragments of the polypeptide may be splice variants, and fragments resulting from in vitro protease activity, without disclosing any actual or prophetic examples on expected performance parameters of any of the possible muteins of SLIM3. The unpredictability of the protein art is evidenced by the Mikayama et al.

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and Voet et al. references which show the large perturbations in function which can occur with mutations of even one amino acid.

Applicant argues that methods of generating fragments of known sequences are routine and conventional in the art and that conventional methods may be used to determine if the particular peptide fragment exhibits the claimed biological activity. However, in the instant claims the limitation that the peptide fragments must be biologically active is not definite (see *infra*). Since insufficient guidance is provided as to what activity the claimed fragments must exhibit, and given the unquestioned evidence of the unpredictability of the protein art provided in the previous Office Action, and that the specification offers insufficient explanation, guidance or working examples as to which amino acids are required to maintain the biological activity of the claimed peptide, it would require undue experimentation for one of skill in the art to practice the claimed invention.

Applicant further argues that the use of the term "fragment" is common in issued patents. However, each application is examined on its own merits, and in this case a *prima facie* case that the claims are not enabled for the scope they encompass has been established.

5. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide

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support for the invention as now claimed: a method comprising a biologically-active-fragment of SLIM3.

Applicant's amendment, Paper No. 9, 12/26/2001, does not provide sufficient direction for the written description for the above mentioned limitations of claim 1. The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide direction for the instant sequence encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above.

Claim Rejections - 35 USC § 112 second paragraph

6. Claims 1-9 stand rejected, and new claims 13-15 are rejected, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record set forth in paper No. 8, 9/24/2001.

Claims 1 and 13 are vague and indefinite in the recitation of the term "biologically active". The term "biologically active" is not defined by the claim, and give no definition of what this activity is. Applicant argues that the one of skill in the art would recognize from the

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specification what was encompassed by the term "biologically active". However, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claims 2-9 stand rejected, and claims 14-15 are rejected, insofar as they depend on the recitation of the term "biologically active".

Conclusion

7. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

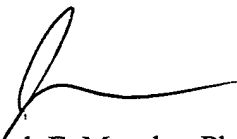
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Advisory Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
February 21, 2002



DAVID S. ROMEO
PRIMARY EXAMINER